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Dockets Management Branch
Division of Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Ladies and Gentlemen:

RE: Docket No. 02D-0039 Comments to Proposed Guidance "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA"

The following comments, filed on behalf of the Orthopedic Surgical Manufacturer's Association (OSMA), are comprised of general comments on the entire guidance and specific comments related to elements within the draft guidance.

General Comments:

1. **General Comment:** The draft guidance appears to have been written to correct what FDA believes to have been a misconception, that all parts of a sterilization system should be considered adjunct to the sterile barrier portion of the system, and thus should be considered Class II devices. The draft guidance, therefore, constitutes the special controls needed for that Class determination. This conclusion, that is supported by the content of the Background and Introduction sections of the Draft Guidance, appears to contradict the contents of the Class designation contained in the Classification Names for Medical Device and In Vitro Diagnostic Products document published by CDRH. The appearance is one of a de facto reclassification of Class I devices (i.e. surgical trays) to Class II, at least insofar as industry has generally understood FDA's publications, without any evidence provided that suggests that the action is taken to avert risk to public health. FDA lacks the statutory authority to act in this fashion. Moreover, there is an AAMI document, AAMI TIR 12, that was written, with FDA input and participation, to establish guidance for sterilization containers and trays. This constitutes a useable special control, obviating the need for significant parts of the proposed guidance. The proposed Guidance appears to be attempting to address a non-existent problem without appropriate statutory authority.

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2. **General Comment:** The document is not clearly written. There is a confusing welter of terms such as "cassettes," "wraps," "containers," "trays," "packaging systems," and "organizers" that are used in different contexts within the document; and they are at times applied in the document in contradiction to longstanding uses and understanding on the part of industry. The statement that there is no consensus definition available (as used for "trays" and "cassettes" in the list of Definitions in the draft guidance) suggests that there was insufficient preparation and communication with the manufacturers and users of sterilization systems and components before the guidance was written. Additional work on the list of devices and consensus definitions for each would seem to be absolutely essential for proper understanding of the guidance in order to apply it.

Specific Comments on Text Elements:

1. **Text:** Page 1, paragraph 2, of the draft document states, "A person intending to market a sterilization packaging system intended for the terminal sterilization of medical devices in health care facilities must submit to FDA, and have cleared, a premarket notification submission prior to introduction of the product into interstate commerce..."
   Comment: It is not clear from this statement where the responsibility for the sterilization packaging system 510(k) actually resides. Should the 510(k) be submitted by the manufacturer selling a sterilization packaging system to the designing/marketing company, or does the responsibility lie with the designing/marketing company (or is it both)?

2. **Text:** Page 2, paragraph 1, of the draft document states, "This guidance includes sterilization trays and cassettes...because they are intended to enclose medical systems for terminal sterilization, and they are considered a medical sterilization packaging system. Therefore, they are Class II devices requiring the submission of a premarket notification [510(k)]."
   Comment 1 to this text: This usage of the terms for cassettes and trays is ambiguous and contradictory with later usage in the document. Under C. Definitions, both Cassettes, Sterilization: (page 3) and Trays: (page 5) are noted as lacking consensus definitions. The document then provides the FDA's definition that clearly identifies them as components of a sterilization system (not as a sterilization packaging system) which requires that they be enclosed in a sterile barrier for function (either sterile wrap or rigid container acting as a sterile barrier).
   Comment 2 to this text: In addition, 21 CFR 880.5850, Sterilization Wrap, reads "...and also to maintain sterility of the enclosed device until used." The guidance properly notes this important distinction in its definition of a sterilization cassette (page 3, C. Definitions) where it states that, "To maintain sterility, they are enclosed in a sterilization wrap." On page 5 of C. Definitions Trays: are defined as being "...either enclosed in sterilization wrap or placed inside a container for sterilization." It is clear that the draft guidance intends maintenance of sterility to be a function of a primary sterile barrier, not the cassette or tray. On page 17, the draft guidance states that, "The cassette itself cannot maintain sterility. No claims can be made for maintenance of sterility unless the cassette is wrapped with sterilization wrap." Trays are not even mentioned in the context of requirements for Microbial Barrier Properties (page 15), Physical Test Methods (page 15), or Sterilization Integrity requirements (page 17), for the maintenance of sterility in sterilized Sterilization Packaging Systems.

Comment 3 to this text: The text of the draft guidance makes tacit or explicit reference to the requirements for testing the microbial barrier properties of the container system and either explicitly excludes cassettes (or in the case of trays excludes them by omission) from participation in the maintenance of sterility. It is agreed that this should be the case. Sterilization Cassettes and Trays are clearly accessories (Page 3, paragraph 1), in that they do not independently function in achieving or maintaining sterility. Sterile barriers should be Class II devices. Those devices that do not participate in the maintenance of sterility (i.e. cassettes and trays) should be Class I. (It should be noted that industry has long held this to be the case, based on the content of the Classification Names documents from FDA, and handled these devices in this fashion with no evidence of problems that can be ascribed to that handling. It would appear to be a contravening of the Least Burdensome requirements of FDAMA to impose demands for submissions for these devices that, absent sterile barrier function, serve only as devices for handling convenience, and have historically been so treated as Class I devices.)
Comment 4 to this text: It is suggested that the requirements for Sterilization Cassettes (page 17) be segregated from those of Sterilization Containers to alleviate the potential confusion between the two devices. (Throughout the draft guidance there seems to be a degree of confusion over these terms.) Use of pictures to represent the devices would be a welcome aid to understanding intended meaning. Moreover, it appears inappropriate to require "Integrity" testing for cassettes (page 17) when, by FDA's definition they cannot show sterilization integrity.

3. **Text:** Page 10, at the first bullet point, states that, "You should submit performance data comparing the characteristics of sterilant penetration of your device with the predicate. Your device should be porous enough to allow adequate sterilant penetration or conductance".
Comment: It was previously acknowledged in this guidance that sterilization cassettes, as an accessory, do not maintain sterility without the benefit of another device (i.e. sterilization wrap). It is the sterile barrier that requires characterization for sterilant penetration relative to the predicate device, not the cassette contained within the sterile barrier. Because of the open design of sterilization cassettes, permeability is not the question that appears to need the generation of data to address.

4. **Text:** Page 10, at the second bullet point, states that, "You should submit performance data comparing the packaging integrity properties of your device with the predicate. To maintain sterility, your device should be impermeable to microorganisms."
Comment: It was previously acknowledged in this guidance that sterilization cassettes, as an accessory, do not maintain sterility without the benefit of another device (i.e. sterilization wrap). In the definition on page 3, it is explicitly stated that, "To maintain sterility, they are enclosed in a sterilization wrap," making reference to sterilization cassettes. Also on page 11 in the last paragraph, it is stated that, "Sterilization cassettes and trays require sterilization wrap." The sterilization cassette or tray does not maintain sterility; the sterilization wrap or rigid sterilization case used by the medical facility is a separate device that is responsible for the maintenance of sterility.

5. **Text:** On page 11, item 2, fourth bullet, cassettes are identified as requiring identification of the sterilization wrap as a specification requirement.
Comment: It does not appear appropriate to identify sterilization wrap, which may be supplied by a number of different manufacturers as a specification requirement for cassettes. The sterilization wrap is procured by the health care facility and applied to devices to be sterilized according the facility's validated procedures. The cassette manufacturer or distributor has no control over how the facility conducts their sterilization processing, nor should they. This is an unwarranted requirement.

6. **Text:** On page 11, item 5 calls for the description of the recommended sterilization process and cycle parameters.
Comment: The sterilization process and the parameters for that process are under the control of the health care facility conducting the sterilization of medical devices using sterilization packaging systems. It is incumbent on cassette (and tray) manufacturer/distributors to show compatibility of the materials of construction with standard sterilization processes. However, cassette manufacturer/distributors can have no control over the specific process used, nor should they be required to specify cycle parameters.

7. **Text:** Page 11, item 6 calls for identification for "Limits of reuse."
Comment: The manufacturer of cassettes or trays cannot accurately predict the limits of reuse for a sterilization cassette or tray. The definition of normal use can vary significantly between end-users with some conducting processing in the health care facility while others may use third-party reprocessors. Because of this, the effects of use vary widely from facility to facility. Moreover, because the cassette or tray participates in the process only in supporting the devices for which sterility is required (not maintaining sterility), it is relatively easy to identify the point at which replacement needs to be made by simple observation. If needed, any limitations on reuse for these devices could be identified using risk analysis/FMEA studies.

8. **Text:** Page 13, item A.1.
Comment: This item provides a list of devices for which sterilant penetration information is required. The list includes devices that function as sterile barriers and those that function only in supporting instruments to be sterilized. The use of the terms could lead one to conclude that they function in the same fashion, although sterilant penetration is really only a significant consideration for those that are sterile barriers.

9. **Text:** Page 14, item B. Package Integrity
Comment: The discussion on Package Integrity is appreciated by industry because the Agency highlights the differences and limitations between microbial challenge tests and physical tests for microbial barrier properties of packaging systems. It is understood that there is a desire to perform whole package integrity test methods to confirm sterile package integrity. However, currently, there are limited test methods to perform such evaluations. Porous materials such as paper and Tyvek severely restrict test methodology for whole package integrity. In addition, test apparatus for ASTM D3078 *Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission* is limited to small

package sizes which would eliminate most of the sterilization packaging systems that are the subject of this draft guidance. It is suggested that the Agency consider adopting the position taken in ISO 11607-1997 *Packaging for terminally sterilized medical devices*, which is an internationally recognized consensus standard. ISO 11607 establishes package integrity and sterility maintenance by demonstrating the continuity and impermeability of the seal using physical methods coupled with microbial barrier property testing of the packaging materials themselves. It might be better to use language for this as follows:

> *While whole package integrity testing is preferred, packaging materials, package size, and test apparatus may limit the ability to do such testing. When whole package integrity tests are not possible, it is sufficient to demonstrate sterile package integrity by demonstrating that the seal is continuous and impermeable using seal integrity tests and by testing the microbial barrier properties of the packaging materials themselves for acceptable performance.*

10. **Text:** Page 15, item 2, Microbial Barrier Properties
Comment: In the Background section on Page 1, sterilization cassettes and trays are identified as "medical sterilization packaging systems." The above text section on microbial barrier properties calls for microbial barrier testing of the "medical device packaging system after sterilization." Elsewhere in the draft guidance, it is made clear that sterilization cassettes and trays cannot function in the maintenance of sterility unless contained within a microbial barrier device, such as sterilization wrap or a rigid sterilization container. The requirement for microbial barrier property testing for cassettes and trays has no scientific basis.

11. **Text:** Page 17, item 5, Sterilization Cassette Integrity states that, "The data should show that the enclosed devices are sterile. The cassette itself cannot maintain sterility. No claims can be made for maintenance of sterility unless the cassette is wrapped with sterilization wrap."
Comment: It is agreed that the sterilization cassette as marketed will not maintain sterility. This is the principle reason why it appears inappropriate to consider this device (along with sterilization trays) as Class II devices under 21 CFR 880.6850. Sterility can only be assured with the use of a cleared microbial barrier device such as sterilization wrap. As noted above, the sterile barriers are separate devices, not provided with or as part of the sterilization tray/cassette devices themselves. Sterilization wrap or rigid sterilization containers are selected and applied by the health care facility for use as sterile barriers within which the cassettes or trays held for sterilization. The wrap or rigid sterilization container is the device which maintains sterility until they are opened so that the sterile contents can be used. The selection and application of the sterile barrier devices are under the control of the health care facility, as is the process that is used to render the devices sterile.

12. **Text:** Page 19, item E, reads in part, "You should provide...method for tracking the device in the labeling. (Please note that tracking refers only to the facility's tracking system...)."
Comment: Manufacturers have no control over, nor even any detailed knowledge of, the tracking systems in use in health care facilities or third-party reprocessors. Consequently, this requirement for labeling/tracking is beyond the control of the tray/cassette

manufacturer/distributor. Manufacturers already label/etch a product part and lot number directly onto the sterilization cassette or tray as required by 21 CFR Part 820. Some manufacturers also incorporate a HIBCC bar code into the labeling that is applied to the cassette or tray.

13. **Text:** Page 20, Item G Biocompatibility
Comment: The tests listed as tests for biocompatibility in this draft guidance are not consistent with the requirements listed in AAMI/ISO 10993-1 with respect to intended user or patient exposure. It is strongly suggested that the AAMI/ISO document be reviewed and modifications made to this draft guidance to apply tests that are consistent with the national and international standard and appropriate to the potential exposure of users and/or patients.

14. **Text:** On Page 21, in the information on Labeling, it reads at the ninth bullet point, "A statement that complex instruments…should be prepared and sterilized according to the instrument manufacturers instructions."
Comment: This requirement appears to exceed the basic purpose of the guidance and imposes burdens on the manufacturers/distributors of sterilization cassettes and trays that are unwarranted and inconsistent with elements of the rest of this draft guidance, especially page 13, item A.1. where performance information is required to show that the sterilant is able to penetrate the sterilization wrap, pouch, cassette, container, or tray and sustain direct contact with the medical instruments inside the package for each sterilization method claimed in labeling.

15. **Text:** Page 22, Sterilization Cassettes
Comment: The first and fourth bullet points are redundant.

16. **Text:** Page 23, V. Sterilization Packaging Systems Checklist, checkpoint on Material composition, physical and chemical properties.
Comment: It is not clear what is envisioned by the agency for "chemical properties," since requirements for this are not addressed elsewhere in the document.

Thank you for your consideration of these comments to the draft guidance.

Very truly yours,

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